Congressional Schedule

• The House and Senate are in recess until Jan. 4, 2007.

• On Dec. 8, 2006, the Senate confirmed Terry L. Cline, Ph.D. as the next Administrator of the Substance Abuse and Mental Health Services Administration.

• On Dec. 9, 2006, the House passed S.3546, the Dietary Supplement and Nonprescription Drug Consumer Protection Act. The bill requires dietary supplement manufacturers to list an address or telephone number on product labels that consumers can use to report serious adverse reactions, and companies to promptly report such information to the Food and Drug Administration (FDA). The new requirement will also apply
to over-the-counter drugs.

- On Dec. 21, 2006, President Bush signed into law H.R. 3248, the "Lifespan Respite Care Act of 2006," which amends the Public Health Service Act to establish a program to assist family caregivers in accessing affordable and high-quality respite care; and H.R. 6342, the "Veterans Programs Extension Act of 2006," which extends certain Department of Veterans Affairs' programs, and makes changes to education benefits and medical facilities and lease authorities.

- President Bush signed HR 6408, the Tax Relief and Health Care Act of 2006, into law on Dec. 20, 2006. The new legislation contains a wide array of provisions, from tax relief to trade measures in Vietnam and various health measures. Among the health provisions included in the bill is the elimination of a scheduled five percent Medicare rate cut for physicians in 2007 and establishes a 1.5 percent incentive increase for doctors who report on quality measures.

- On Dec. 19, 2006, President Bush signed S. 3678, the "Pandemic and All-Hazards Preparedness Act," into law. This legislation authorizes appropriations through 2011 to improve bioterrorism and other public health emergency planning and preparedness activities, and establishes the Biomedical Advanced Research and Development Authority within the Department of Health and Human Services for the advanced research and development of medical countermeasures.


Military Health Care News

- Robert E. Gates was sworn in as Secretary of Defense on Dec. 18, 2006.

- On Dec. 19, 2006, the Department of Defense (DoD) announced its new approach for governance and management of the military health system (reported in the Dec. 8 Update). The plan, which was approved by Deputy Secretary of Defense Gordon England on Nov. 27, 2006, is a conceptual framework for the new governance. The concept creates joint oversight and leadership of several key functional areas (education and training, medical research, health care delivery in major U.S. markets and critical shared services) across the health system.

Objectives of the new approach are to streamline operations, create greater efficiencies and cost savings, improve coordination of medical services, improve support to war-fighters, leverage better medical research, and create greater jointness and standardization in training of military medical personnel. This new approach for governance responds to departmental direction that the undersecretary of defense for personnel and readiness, Joint Staff, and military services work together to improve management performance and efficiency of the military health system. The transition and realignment is scheduled to be
• The Department of Defense (DoD) released “Policy Guidance for Deployment-Limiting Psychiatric Conditions and Medications,” on Dec. 14, 2006. The policy improves the guidance for military personnel with deployment-limiting psychiatric conditions, and for those who are prescribed psychiatric medications. The new policy satisfies many requirements established in the 2007 National Defense Authorization Act signed into law on Sept. 29, 2006. Section 738 of the law requires DoD to specify conditions and treatments that preclude a Service member from deploying to a combat or contingency operation.

While not altering or replacing existing accession, retention, and general fitness for duty standards, the new guidance standardizes deployment-related mental health policy across the Service branches. The guidelines stipulate that few medications are inherently disqualifying for deployment. However, lithium and anticonvulsants to control manic-depressive bipolar illness are considered disqualifying medications, as are antipsychotic drugs for psychotic, bipolar and chronic insomnia symptoms. Psychotic and bipolar spectrum disorders are also disqualifying.

• On Dec. 18, 2006, Express Scripts Inc. bid $26 billion in cash and stock for Caremark Rx Inc., possibly killing an existing all-stock takeover offer from drug chain CVS Corp. Based on Dec. 15 closing prices, the offer carries a value of $58.50 per Caremark share, a 15 percent premium over the CVS bid. The bid could set off a tug-of-war between Express Scripts and CVS/pharmacy. Last month, Caremark Rx and CVS/pharmacy, the country's second-largest drugstore chain, agreed to merge in a deal some believe could transform the drug industry. If the deal goes through, Caremark stockholders would own approximately 57 percent of the combined company, and Express Scripts stockholders would own approximately 43 percent.

The combination will create the world's pre-eminent pharmacy benefit management company. Maryland Heights, Mo.-based Express Scripts is half the size of Caremark. The two companies are the third- and second-largest pharmacy benefit management companies. The race to consolidate in the drug industry comes at a time of tremendous pressure to lower prices. Wal-Mart recently announced it would sell some generic drugs for $4. That leaves companies like Express Scripts and Caremark Rx, who act as middlemen between drug companies and employees, to struggle to reduce costs.

• SRA International, Inc., a technology and strategic consulting services and solutions company, announced that it has been awarded a competitive task order by the U.S. Department of Defense (DoD) TRICARE Management Activity (TMA). SRA will provide technical and analytical services to help TMA improve the efficiency and effectiveness of Military Health System operations, management, and health care data quality maintenance. The task order, awarded under the General Services Administration Federal Supply Schedule, has an estimated value of $13.6 million over five years if all options are exercised.

The Office of Business and Economic Analysis (BEA) of the TRICARE Management Activity supports performance-based decision-making and program execution throughout the Military Health System. SRA has supported the BEA office for the past 13 years with analytical and data research and health and fiscal policy development. Under this new contract, SRA will continue recent work in bio-statistical, financial,
workload, and manpower studies and analysis. Services will include program management; health policy and data analysis; DoD beneficiary analysis; and curriculum development for educational courses. http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/12-20-2006/0004494567&EDATE=

• In one of his last acts as Defense Secretary, Donald Rumsfeld presented the Department of Defense Medal for Distinguished Public Service to 32 Pentagon employees. Those honored included Dr. David S.C. Chu, under secretary of defense for personnel and readiness, for the department's language and regional training initiative and Dr. William Winkenwerder, Jr., assistant secretary of defense for health affairs, for military medicine enhancements.

Veterans Health Care News

• Lucille B. Beck, Veteran Affairs’ director of Audiology and Speech Pathology and chief consultant for its Rehabilitation Services, received the “Honors of the Association” Award from the American Speech-Language-Hearing Association. The award recognizes distinguished contributions to the field of speech, language and hearing and is the highest honor the association confers. http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1259

• The Department of Veterans Affairs (VA) announced two new Fisher Houses will be built to provide safe, comfortable and affordable housing for families of veterans being treated at VA facilities in Seattle, Wash., and Boston, Mass. The new Fisher House will be built on the grounds of VA medical centers in Seattle and in Boston. Construction is scheduled to begin in 2007. Fisher Houses are built through public donations and contributions from the Fisher House Foundation. VA assumes responsibility for operating costs of the finished homes. Currently, VA has eight Fisher Houses in: Albany, N.Y.; Bay Pines, Fla.; Cincinnati; Denver; Houston; Minneapolis; Palo Alto, Calif.; and West Palm Beach, Fla. A ninth Fisher House is under construction in Tampa, with completion due in early 2007. http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1260 and http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1261

• The Department of Veterans Affairs (VA), announced it will open a new outreach clinic in the Yuma/Burlington/Goodland area of Colorado and Kansas. The new clinic will provide basic primary care and mental health services, including medical evaluations and the diagnosis and treatment of conditions that do not require hospitalization or specialty care. The clinic will be open five half-days a week, with a registered nurse onsite during operating hours. Telemedicine (the use of telecommunications technology to provide health care from distant locations) will link the clinic with additional services at other VA clinics and hospitals. Currently, the 4,000 veterans VA serves in the nine-county area where the new clinic will open are not within an hour’s driving distance of a location in which VA health care is provided. Because 44 percent of the area’s population is 65 or older, it is difficult for many area residents to visit a distant VA facility for care, especially during the winter months. VA expects that the clinic will open within the next few months. VA operates two medical centers and 11 community-based outpatient clinics in Colorado.
• The Department of Veterans Affairs (VA) is reaching out to inform wartime veterans and surviving spouses of deceased wartime veterans about an under-used, special monthly pension benefit called Aid and Attendance. The Aid and Attendance pension benefit may be available to wartime veterans and surviving spouses who have in-home care or who live in nursing-homes or assisted-living facilities. To qualify, claimants must be incapable of self support and in need of regular personal assistance. For a wartime veteran or surviving spouse to qualify for this special monthly pension, the veteran must have served at least 90 days of active military service, one day of which was during a period of war, and be discharged under conditions other than dishonorable.

Wartime veterans who entered active duty on or after September 8, 1980, (October 16, 1981, for officers) must have completed at least 24 continuous months of military service or the period for which they were ordered to active duty. If all requirements are met, VA determines eligibility for the Aid and Attendance benefit by adjusting for un-reimbursed medical expenses from the veteran’s or surviving spouse’s total household income. If the remaining income amount falls below the annual income threshold for the Aid and Attendance benefit, VA pays the difference between the claimant’s household income and the Aid and Attendance threshold.

Health Care News

• The United Nations General Assembly passed a landmark Resolution on Dec. 21, 2006, recognizing the global threat of the diabetes epidemic. For the first time, governments have acknowledged that a non-infectious disease poses as serious a threat to world health as infectious diseases like HIV/AIDS, tuberculosis and malaria. The International Diabetes Federation (IDF) leads the Unite for Diabetes campaign, which aims to draw attention to the seriousness of diabetes and encourage action to fight the epidemic. Since its inception the campaign has aimed for a UN Resolution. The Unite for Diabetes campaign has brought together the largest ever diabetes coalition, including patient organizations from over 150 countries, the majority of the world’s scientific and professional diabetes societies, many charitable foundations, service organizations and industry. The Resolution designates World Diabetes Day, November 14th, as a United Nations Day to be observed every year starting in 2007. It calls on all UN Member States to observe the day and on all nations to develop national policies for the prevention, treatment and care of diabetes.

• The Centers for Medicare and Medicaid Services (CMS) announced that the Medicare Coverage Advisory Committee has been re-chartered through autumn 2008. As part of this re-charter, the agency has updated the Committee’s role in the Medicare national coverage process to include re-designating the Committee from the Medicare Coverage Advisory Committee (MCAC) to the Medicare Evidence Development & Coverage Advisory Committee (MedCAC); expanding its responsibilities to advise CMS as part of its coverage with evidence development (CED) activities. The CED initiative involves the issuance of national coverage determinations that include, as a condition of payment, requirements for developing additional clinical data on a particular medical technology; and formalizes the role of patient
advocates on the Committee. Since 2005, each Committee meeting has included a patient advocate as a voting member on each expert panel. By establishing the patient advocate as a permanent MedCAC role, CMS is ensuring that the beneficiary community is represented on the panels—these advocates will identify issues most important to patients, communicate the patient perspective, and vote on the Committee’s recommendations with patients’ general interests in mind.

Since 1998, the Committee has provided recommendations about specific issues of Medicare coverage and reviewed and commented upon proposed or existing Medicare coverage policies. The Committee consists of up to 100 appointed members, who are selected for their expertise in clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, medical ethics, and other related disciplines.

To accompany the changes in the MedCAC charter, CMS has issued a guidance document “Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee.” This document is consistent with Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, and is in line with CMS’ goal of continuing to develop a more open, transparent, and understandable national coverage process. CMS News Release 12-13-2006

• The Department of Health and Human Services (HHS) launched the National Clearinghouse for Long-Term Care Information Web site on Dec. 14, 2006. The new Web site provides comprehensive information about long-term care planning, services and financing options, along with tools to help people begin the planning process. The clearinghouse Web site is designed to increase public awareness about the risks and costs of long-term care and the potential need for services, and to provide objective information to help people plan for the future. It contains objective information to help consumers decide whether to purchase long-term care insurance or to pursue other private market alternatives that pay for long-term care; information about states with long-term care partnerships under Medicaid; and information about the availability and limitations of coverage for long-term care under Medicaid. The National Clearinghouse for Long-Term Care Information Web site helps support the principles of the "Choices for Independence Initiative," included in the recently reauthorized Older Americans Act (OAA), signed into law by President Bush in October. http://www.hhs.gov/news/press/2006pres/20061215.html

• The United States has formally accepted the revised International Health Regulations (IHR), and will begin the process of implementing these new international rules immediately instead of waiting for them to take effect in June 2007. The International Health Regulations are an international legal instrument that governs the roles of the World Health Organization (WHO) and its member countries in identifying and responding to and sharing information about public health emergencies of international concern. The updated rules are designed to prevent and protect against the international spread of diseases, while minimizing interference with world travel and trade.

Under the revised regulations, countries that have accepted the IHRs have much broader responsibility to take preventive measures against, as well as to detect and respond to, public-health emergencies of international concern. The regulations give the WHO clearer authority to recommend to its member states measures that will help contain the international spread of disease, including public-health actions to be taken at ports, airports, land borders and on means of transport that involve international travel. The
revised regulations include a list of four diseases -- smallpox, polio, Severe Acute Respiratory Syndrome (SARS) and new strains of human influenza—whose occurrence member states must immediately report to the WHO. In addition, the regulations provide an algorithm to determine whether other incidents, including those of a biological, chemical or radiological nature, constitute public-health events of international concern. The rules also provide specific procedures and timelines for announcing and responding to public health events of international concern.

The United States has accepted the IHRs with the reservation that it will implement them in line with U.S. principles of federalism. In addition, the U.S. Government has also submitted three understandings: incidents that involve the natural, accidental or deliberate release of chemical, biological or radiological materials are notifiable under the IHRs; countries that accept the IHRs are obligated to report potential public health emergencies that occur outside their borders to the extent possible; and the IHRs do not create any separate private right to legal action against the federal government.

• The Food and Drug Administration (FDA) approved Cyanokit (containing the drug hydroxocobalamin, intravenous tubing and a sterile spike for reconstituting the drug product with saline) for the treatment of known or suspected cyanide poisoning. The approval, which is based on evidence of the drug's effectiveness when tested in animals, improves the nation's ability to respond to emergencies, including a potential attack by terrorists. Cyanokit received a priority review and was approved under the Animal Efficacy Rule, which allows use of animal data for evidence of a drug's effectiveness for certain conditions when the drug cannot be ethically or feasibly tested in humans. Cyanokit is manufactured for EMD Pharmaceuticals, Inc. by Merck Sante s.a.s. in Semoy, France and packaged by Dey Laboratories of Napa, California. [http://www.fda.gov/bbs/topics/NEWS/2006/NEW01531.html](http://www.fda.gov/bbs/topics/NEWS/2006/NEW01531.html)

• Acting Surgeon General Kenneth P. Moritsugu, M.D., M.P.H., announced two new Family History demonstration projects - focused on Alaska Native and urban Appalachian populations. The one-year projects, each of which will receive $100,000, will develop community-based models to increase awareness among the public and health care professionals about the value of family history information in promoting health and preventing disease.

In the first project, a multi-institution team will work with Appalachian populations living in the greater Cincinnati metropolitan area to develop ways of educating people with low levels of literacy about the importance of family health history and raise awareness among health care professionals working in the targeted areas about the need to collect family health information.

The second project, led by Ruth Etzel, M.D., at the Southcentral Foundation, which is an Alaska Native health care organization located in Anchorage, will develop tools and methods for creating a common understanding about the role and importance of family health history among Southcentral Foundation's staff. The foundation employs more than 1,300 people, of which more than half are Alaska Natives. This project will receive co-funding from NHGRI and the NIH's National Center on Minority Health and Health Disparities.

• On Dec. 11, 2006, the Food and Drug Administration (FDA) proposed significant regulatory changes to make experimental drugs more widely and easily available to seriously ill patients with no other treatment options and to clarify the circumstances and the costs for which a manufacturer can charge for an experimental drug. Under the proposed rule, expanded access for experimental drugs would be available to individual patients, small patient groups, and larger populations under a treatment plan when there is no satisfactory alternative therapy to diagnose, monitor or treat the disease or condition. The most significant proposals would: modernize applicable regulations to include all circumstances under which access to experimental drugs is permitted; make experimental drugs more widely available in appropriate situations by establishing criteria that link the level of evidence needed to support the use of an experimental drug to the seriousness of the disease and the number of patients likely to be treated with the drug; and revise the current regulation regarding manufacturers' recovery of the costs of an experimental drug. http://www.fda.gov/bbs/topics/NEWS/2006/NEW01520.html

• On Dec. 15, 2006, the Department of Health and Human Services (HHS) named Thomas E. Lorentzen as the new director for Region IX, based in San Francisco. In his new position, Lorentzen will be Secretary Leavitt's representative responsible for dealings with state, local and tribal government organizations and will promote the Secretary's commitment to state and local health agencies. The region comprises the states of Arizona, California, Hawaii and Nevada, as well as Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau. His appointment is effective immediately. http://www.hhs.gov/news/press/2006pres/20061215a.html

• The Centers for Medicare and Medicaid Services (CMS) announced it will conduct its second annual provider satisfaction survey of Medicare fee-for-service contractors who process and pay more than $280 billion in Medicare claims each year. The survey focuses on seven major parts of the provider-contractor relationship -- provider communications, provider inquiries, claims processing, appeals, provider enrollment, medical review, and provider audit and reimbursement. CMS will send the survey to about 35,000 randomly selected providers, including physicians and other health care practitioners, suppliers and institutional facilities that serve Medicare beneficiaries across the country.

Those providers selected to participate in the survey will be notified by mail during the first week of January 2007. The survey is designed so that it can be completed in about 15 minutes and providers can submit their responses via a secure Web site, mail, fax or over the telephone. CMS will ask providers to respond by February 2007. The results of the first Medicare Contractor Provider Satisfaction Survey (MCPSS), released in September 2006, showed that the vast majority—85 percent—of health care providers are satisfied with the customer service, claims processing and educational activities provided by these contractors. CMS 12-19-2006 NR

Reserve/Guard

• The total number of Guard and Reserve currently on active duty has decreased by 3,064 from the last report to 92,767. The totals for each service are Army National Guard and Army Reserve, 76,720; Navy
Reserve, 4,923; Air National Guard and Air Force Reserve, 5,324; Marine Corps Reserve, 5,436; and the Coast Guard Reserve, 363.

www.defenselink.mil

Contracts/Procurements

- The Department of Veterans Affairs Health Administration Center issued a Request for Information (RFI) to determine estimated duration, resources needed and cost in performing IT development to integrate Electronic Medicare Crossover claims processing with existing technology at the HAC through its existing IT Infrastructure. The proposed solution will be designed and developed within the existing architecture and framework of the HAC's existing legacy systems. The current response date is Feb. 18, 2006. For more information, contact Cassandra Williams, contracting officer at (303) 398-7139 or via e-mail at cassandra.williams3@med.va.gov. http://www.fbo.gov/spg/VA/VAHAC741/VAHAC741/741%2D01%2D07/SynopsisR.html

- U.S. Army Medical Command, Center for Health Care Contracting Office in Fort Sam, Texas announced it has awarded Donald L. Mooney Enterprises, LLC of Universal City, Texas $1.8 million to provide personnel for the Army’s post-deployment health reassessment (PDHRA) services. http://www.fbo.gov/spg/USA/MEDCOM/DADA10/Awards/W81K04-07-D-0010Ln0001AA_to_0001AC_;_0003AA_to_0003AC_;html

Reports/Policies

- The GAO issued “Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising,” (GAO-07-54) on Nov. 16, 2006 and published it Dec. 14, 2006. In the report, the GAO discussed trends in drug company spending on DTC advertising and other activities; what is known about the relationship between DTC advertising and drug spending and utilization; the DTC advertising materials FDA reviews; the number of regulatory letters that cited DTC materials and FDA's process for issuing those letters; and the effectiveness of these letters at limiting the dissemination of DTC advertising. GAO reviewed research literature, analyzed FDA's processes, and examined FDA documentation. http://www.gao.gov/new.items/d0754.pdf

- The Institute of Medicine (IOM) released “Modeling Community Containment for Pandemic Influenza: A Letter Report,” on Dec. 11, 2006. The report found through its computer models and analyses of past flu outbreaks that there is a role for community-wide intervention—such as isolating infected people or voluntary quarantine—to control illnesses and deaths during the next pandemic flu. It cautions that government and community leaders should not overstate the certainty about their effectiveness. http://books.nap.edu/openbook.php?record_id=11800&page=1
The Congressional Budget Office (CBO) released “Designing a Premium Support System for Medicare,” in December 2006. The CBO study examined the key decisions to be confronted in designing a premium support system for Medicare and the implications of alternative design choices for federal spending and beneficiaries’ premiums. [http://www.cbo.gov/ftpdocs/76xx/doc7697/12-08-Medicare.pdf](http://www.cbo.gov/ftpdocs/76xx/doc7697/12-08-Medicare.pdf)


Legislation

**H.R.6425** (introduced Dec. 8, 2006): To amend the Juvenile Justice and Delinquency Prevention Act of 1974 to improve the health and well-being of maltreated infants and toddlers through the creation of a National Court Teams Resource Center, to assist local Court Teams, and for other purposes was referred to the House Committee on Education and the Workforce. 
Sponsor: Representative Ileana Ros-Lehtinen [FL-18]

**H.R.6431** (introduced Dec. 8, 2006): To direct the Secretary of Health and Human Services to approve the Change In Scope Request submitted by Family HealthCare Network to the Bureau of Primary Health Care on Dec.8, 2005 was referred to the House Committee on Energy and Commerce. 
Sponsor: Representative Devin Nunes [CA-21]

**S.4122** (introduced Dec. 8, 2006): A bill to amend the Indian Health Care Improvement Act to revise and extend that Act was referred to the Committee on Indian Affairs. 
Sponsor: Senator John McCain [AZ]
• There are no hearings scheduled.

Meetings / Conferences

• The Food and Drug Administration (FDA) will hold a public workshop on issues related to the application process for seeking approval for marketed unapproved drugs on Jan. 9, 2007 in Bethesda, Md. http://www.fda.gov/cder/drug/unapproved_drugs.


• The 2007 HIMSS will be held Feb. 25 to March 1, 2007, in New Orleans, La. http://www.himss07.org/

• The 2007 International Symposium on Antimicrobial Agents and Resistance (ISAAR) will be held on March 7-9, 2007, in Singapore. http://www.isaar.org/sub01_invitation.asp

• 46th Annual Research in Medical Education (RIME) Conference will be held Nov. 2-7, 2007, in conjunction with the AAMC Annual Meeting in Washington, D.C.

If you need further information on any of the items in the Federal Health Update, please contact Kate Connelly Theroux at (703) 447-3257 or by e-mail at kate@usminstitute.org. To subscribe, please visit http://usminstitute.org/subscriber.cfm. To unsubscribe, please send an email to update@usminstitute.org with UNSUBSCRIBE as the subject.